Test Type: CHRONIC

### P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 12/17/2009 AVERAGE SEVERITY GRADES[b]

Pyrogallol CAS Number: 87-66-1

Time Report Requested: 08:48:44 First Dose M/F: 09/15/04 / 09/16/04

Lab: BAT

F1\_R2

Species/Strain: RATS/F 344/N

**Route: SKIN APPLICATION** 

**C Number:** C99032

**Lock Date:** 09/07/2007

Cage Range: ALL

Date Range: ALL

Reasons For Removal: ALL

Removal Date Range: ALL

Treatment Groups: Include ALL

Study Gender: Both

**TDMSE Version:** 2.2.0

**Route: SKIN APPLICATION** 

Species/Strain: RATS/F 344/N

#### P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 12/17/2009 AVERAGE SEVERITY GRADES[b]

Pyrogallol **CAS Number:** 87-66-1

Time Report Requested: 08:48:44 First Dose M/F: 09/15/04 / 09/16/04

FISCHER 344 RATS MALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
Disposition Summary				
Animals Initially In Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	17	14	15	17
Natural Death	10	8	7	5
Survivors				
Natural Death		2		
Terminal Sacrifice	23	26	28	28
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Esophagus	(50)	(50)	(50)	(50)
Periesophageal Tissue, Hemorrhage	1 [4.0]			
Periesophageal Tissue, Inflammation	1 [2.0]			
Intestine Large, Cecum	(49)	(50)	(50)	(50)
Inflammation		2 [2.5]		
Necrosis		1 [3.0]		
Thrombosis		1 [3.0]	1 [3.0]	
Intestine Large, Colon	(50)	(50)	(50)	(50)
Hyperplasia, Lymphoid		1 [3.0]		
Parasite Metazoan	2		1	6
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Parasite Metazoan	4	5	3	4
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Inflammation			1 [4.0]	
Ulcer			1 [4.0]	
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Inflammation			1 [2.0]	
Epithelium, Dysplasia	1 [2.0]			
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Inflammation				1 [2.0]
Peyer's Patch, Inflammation, Granulomatous		1 [1.0]		
Liver	(50)	(50)	(50)	(50)
Angiectasis	3 [2.0]	2 [2.0]		1 [2.0]

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

**Route: SKIN APPLICATION** 

Species/Strain: RATS/F 344/N

#### P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 12/17/2009 AVERAGE SEVERITY GRADES[b]

Pyrogallol **CAS Number:** 87-66-1

Time Report Requested: 08:48:44 First Dose M/F: 09/15/04 / 09/16/04

SCHER 344 RATS MALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG	
Basophilic Focus	8	8	11	8	
Clear Cell Focus	18	17	21	21	
Congestion, Acute	1 [2.0]	17	21	21	
Degeneration, Cystic	1 [2.0]	6 [1.5]	1 [2.0]	1 [1.0]	
Eosinophilic Focus	3	2	1 [2.0]	2	
Fatty Change	1 [2.0]	3 [2.3]	1 [3.0]	3 [3.0]	
Hematopoietic Cell Proliferation	1 [2.0]	3 [2.3]	1 [3.0]	2 [1.0]	
Hemorrhage			1 [3.0]	2 [1.0]	
Hepatodiaphragmatic Nodule	3	2	1 [3.0] 5	4	
Inflammation	19 [1.0]	17 [1.1]	17 [1.1]	17 [1.1]	
Mixed Cell Focus	19 [1.0] 8	6	6	5	
Bile Duct, Cyst	O	Ü	1 [3.0]	3	
	20 [4 4]	24 [4 0]		26 [4 4]	
Bile Duct, Hyperplasia	28 [1.1]	24 [1.0]	27 [1.1]	26 [1.1]	
Centrilobular, Fibrosis	1 [1.0]	4 [0 0]	1 [3.0]		
Hepatocyte, Atrophy	4 [4 0]	1 [2.0]	1 [4.0]		
Hepatocyte, Degeneration	1 [1.0]	1 [2.0]	4.54.03	5.14.03	
Hepatocyte, Necrosis	1 [3.0]	5 [2.2]	4 [1.3]	5 [1.8]	
Hepatocyte, Regeneration	1 [2.0]		1 [3.0]		
Hepatocyte, Vacuolization Cytoplasmic	19 [1.2]	20 [1.2]	24 [1.2]	18 [1.1]	
Kupffer Cell, Pigmentation				1 [1.0]	
Portal, Fibrosis	3 [1.0]	6 [1.0]	9 [1.0]	6 [1.0]	
Vein, Thrombosis		1 [4.0]			
Mesentery	(9)	(2)	(3)	(5)	
Necrosis	7 [3.0]	2 [3.0]	3 [3.0]	4 [3.0]	
Oral Mucosa	(2)	(1)	(4)	(3)	
Gingival, Inflammation	2 [2.0]	1 [3.0]	2 [2.0]	3 [2.7]	
Pharyngeal, Hyperplasia			2 [3.5]		
Pancreas	(50)	(50)	(50)	(50)	
Acinus, Atrophy	28 [1.6]	31 [1.8]	28 [1.7]	31 [2.0]	
Acinus, Hyperplasia	3 [1.3]	8 [1.8]	4 [2.0]	1 [3.0]	
Duct, Cyst	5 [1.4]	4 [1.5]	3 [1.7]	4 [1.5]	
Salivary Glands	(50)	(50)	(50)	(50)	
Hyperplasia		1 [1.0]			
Inflammation		-	1 [4.0]	1 [1.0]	
Duct, Cyst			1 [4.0]		
Stomach, Forestomach	(50)	(50)	(50)	(50)	

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

**Route: SKIN APPLICATION** 

Species/Strain: RATS/F 344/N

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 12/17/2009 AVERAGE SEVERITY GRADES[b]

Pyrogallol **CAS Number: 87-66-1** 

Time Report Requested: 08:48:44 First Dose M/F: 09/15/04 / 09/16/04

FISCHER 344 RATS MALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG	
Fibracia.	4 [0 0]				
Fibrosis	1 [3.0]	4 [0 0]	4 [4 0]	E [4 0]	
Inflammation	2 [1.5]	1 [2.0]	1 [4.0]	5 [1.8]	
Perforation	4.54.01	1	7 [0 7]	4 [0 5]	
Ulcer	4 [4.0]	6 [3.7]	7 [3.7]	4 [3.5]	
Epithelium, Hyperplasia	2 [1.5]	2 [2.5]	4 [2.5]	6 [2.0]	
Stomach, Glandular	(50)	(50)	(50)	(50)	
Congestion		1 [4.0]			
Erosion	2 [2.0]	4 [2.8]		3 [2.0]	
Inflammation		4 [1.3]		3 [1.0]	
Ulcer			1 [2.0]		
Epithelium, Hyperplasia		2 [2.0]	1 [3.0]		
Glands, Cyst		1 [1.0]	1 [3.0]		
Tongue	(1)	(0)	(0)	(2)	
Epithelium, Hyperplasia				1 [3.0]	
CARDIOVASCULAR SYSTEM					
Heart	(50)	(50)	(50)	(50)	
Cardiomyopathy	46 [2.3]	45 [2.4]	46 [2.4]	47 [2.1]	
Atrium, Thrombosis		2 [3.0]		1 [4.0]	
Myocardium, Inflammation				1 [3.0]	
Valve, Thrombosis				1 [4.0]	
Ventricle, Thrombosis				2 [3.0]	
ENDOCRINE SYSTEM					
Adrenal Cortex	(50)	(50)	(50)	(50)	
Atrophy	(55)	(00)	(00)	1 [4.0]	
Degeneration, Cystic		1 [3.0]	1 [3.0]	. []	
Hematopoietic Cell Proliferation		1 [0.0]	1 [1.0]		
Hemorrhage		1 [3.0]	1 [2.0]		
Hyperplasia	19 [1.2]	21 [1.4]	29 [1.5]	20 [1.5]	
Hypertrophy	7 [1.9]			4 [2.3]	
Mineralization	7 [1.9]	10 [1.5]	10 [1.3]		
			1 [4 0]	1 [1.0]	
Necrosis			1 [4.0]	1 [4.0]	

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

**Route: SKIN APPLICATION** 

Species/Strain: RATS/F 344/N

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 12/17/2009 AVERAGE SEVERITY GRADES[b]

Pyrogallol **CAS Number: 87-66-1** 

Time Report Requested: 08:48:44 First Dose M/F: 09/15/04 / 09/16/04

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG	
Vacuolization Cytoplasmic	27 [1.6]	18 [1.5]	23 [1.5]	19 [1.4]	
Capsule, Fibrosis, Focal				1 [2.0]	
Adrenal Medulla	(50)	(50)	(50)	(50)	
Angiectasis				1 [2.0]	
Hemorrhage		1 [3.0]		1 [3.0]	
Hyperplasia	16 [1.8]	18 [2.2]	20 [2.1]	18 [1.8]	
Infiltration Cellular, Mononuclear Cell				1 [2.0]	
Mineralization				1 [2.0]	
Necrosis			1 [4.0]		
Islets, Pancreatic	(50)	(50)	(50)	(50)	
Hyperplasia				1 [3.0]	
Parathyroid Gland	(50)	(49)	(47)	(49)	
Cyst		1 [3.0]			
Hyperplasia		3 [2.0]			
Pituitary Gland	(50)	(49)	(50)	(50)	
Hemorrhage		1 [4.0]		2 [2.0]	
Pigmentation, Hemosiderin				1 [2.0]	
Pars Distalis, Atrophy	1 [3.0]			3 [4.0]	
Pars Distalis, Cyst		2 [1.5]		4 [1.0]	
Pars Distalis, Hyperplasia	11 [1.8]	10 [2.3]	12 [2.8]	13 [2.2]	
Pars Intermedia, Hyperplasia		1 [1.0]	1 [1.0]		
Thyroid Gland	(50)	(50)	(50)	(50)	
Cyst	, ,	1 [3.0]	, ,	, ,	
Inflammation				1 [1.0]	
C-cell, Hyperplasia	18 [1.4]	19 [1.3]	21 [1.4]	18 [1.8]	

#### **GENERAL BODY SYSTEM**

None

### **GENITAL SYSTEM**

Epididymis	(50)	(50)	(50)	(50)
Inflammation		1 [2.0]	2 [1.0]	
Penis	(0)	(0)	(1)	(0)

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

**Route: SKIN APPLICATION** 

Species/Strain: RATS/F 344/N

### P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 12/17/2009 AVERAGE SEVERITY GRADES[b]

Pyrogallol CAS Number: 87-66-1

Time Report Requested: 08:48:44

First Dose M/F: 09/15/04 / 09/16/04

FISCHER 344 RATS MALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG	
Congestion			1 [1.0]		
Preputial Gland	(50)	(50)	(50)	(50)	
Inflammation	2 [1.5]	8 [2.4]	5 [1.2]	7 [1.7]	
Duct, Hyperplasia, Squamous	2 [1.0]	0 [2.4]	5 [1.2]	1 [1.0]	
Prostate	(50)	(50)	(50)	(50)	
Inflammation	44 [1.6]	45 [2.2]	48 [2.4]	44 [1.9]	
Epithelium, Hyperplasia	4 [1.0]	8 [1.5]	5 [1.0]	5 [1.4]	
Epithelium, Metaplasia, Squamous	(==)	(==)	1 [2.0]	1 [1.0]	
Seminal Vesicle	(50)	(50)	(50)	(50)	
Inflammation		1 [3.0]			
Bilateral, Atrophy			1 [2.0]		
Testes	(50)	(50)	(50)	(50)	
Cyst			2 [4.0]	1 [4.0]	
Mineralization			2 [1.5]		
Arteriole, Inflammation		1 [2.0]			
Bilateral, Germinal Epithelium, Atrophy		3 [2.7]		1 [4.0]	
Germinal Epithelium, Atrophy	5 [1.6]	4 [3.8]	7 [3.1]	9 [2.6]	
Interstitial Cell, Hyperplasia	11 [1.2]	13 [1.4]	5 [2.0]	8 [1.5]	
HEMATOPOIETIC SYSTEM					
Bone Marrow	(50)	(50)	(50)	(50)	
Hemorrhage	()	1 [3.0]	(7	()	
Hyperplasia	10 [3.9]	11 [3.4]	11 [3.6]	9 [3.9]	
Infiltration Cellular, Histiocyte	. 0 [0.0]	[0]	[0.0]	1 [1.0]	
Myelofibrosis		1 [3.0]	1 [2.0]	. [5]	
Lymph Node	(10)	(8)	(4)	(7)	
Degeneration, Cystic	(10)	(0)	1 [2.0]	(,,	
Deep Cervical, Degeneration, Cystic		1 [3.0]	1 [2.0]		
Deep Cervical, Hemorrhage		1 [0.0]		2 [2.5]	
Mediastinal, Degeneration, Cystic	2 [2.0]	1 [3.0]		ے رح.ن]	
Mediastinal, Hemorrhage	ک [ک.∪]	2 [2.5]			
Mediastinal, Hyperplasia		2 [2.5] 1 [3.0]			
Mediastinal, Hyperplasia Mediastinal, Hyperplasia, Lymphoid					
	2 [2 5]	1 [2.0]	1 [2 0]		
Mediastinal, Hyperplasia, Plasma Cell	2 [2.5]	1 [2.0]	1 [3.0]		

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

**Route: SKIN APPLICATION** 

Species/Strain: RATS/F 344/N

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 12/17/2009 AVERAGE SEVERITY GRADES[b]

Pyrogallol **CAS Number: 87-66-1** 

Time Report Requested: 08:48:44 First Dose M/F: 09/15/04 / 09/16/04

FISCHER 344 RATS MALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG	
Pancreatic, Degeneration, Cystic	1 [3.0]				
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)	
Degeneration, Cystic	( )	4 [1.5]	1 [2.0]	5 [2.0]	
Hemorrhage		• •		2 [3.5]	
Hyperplasia, Histiocytic			2 [1.5]		
Hyperplasia, Plasma Cell			1 [3.0]		
Infiltration Cellular, Histiocyte				1 [2.0]	
Necrosis, Lymphoid		2 [2.5]			
Spleen	(50)	(50)	(50)	(50)	
Congestion	, ,	, ,	1 [3.0]	,	
Hematopoietic Cell Proliferation				1 [2.0]	
Hyperplasia, Lymphoid	3 [1.7]	3 [2.0]	1 [2.0]	2 [1.5]	
Infarct	2 [3.5]	2 [2.5]	3 [3.7]	1 [3.0]	
Necrosis, Lymphoid		1 [3.0]			
Necrosis, Focal		1 [3.0]			
Thrombosis				1 [3.0]	
Capsule, Fibrosis		1 [2.0]		1 [2.0]	
Capsule, Inflammation				1 [2.0]	
Lymphoid Follicle, Atrophy		1 [3.0]	2 [2.0]		
Lymphoid Follicle, Depletion Cellular		1 [4.0]			
Thymus	(47)	(48)	(48)	(47)	
Cyst			1 [2.0]		
Ectopic Parathyroid Gland				1 [1.0]	
Fibrosis			1 [2.0]		
Epithelial Cell, Hyperplasia				1 [4.0]	
INTEGUMENTARY SYSTEM					
Mammary Gland	(50)	(49)	(50)	(50)	
Inflammation	,	1 [1.0]	, ,	, ,	
Duct, Cyst	1 [3.0]				
Duct, Dilatation	1 [2.0]				
Skin	(50)	(50)	(50)	(50)	
Abscess		1 [4.0]			
Fibrosis				1 [3.0]	

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

**Route: SKIN APPLICATION** 

Species/Strain: RATS/F 344/N

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 12/17/2009 AVERAGE SEVERITY GRADES[b]

Pyrogallol **CAS Number:** 87-66-1

Time Report Requested: 08:48:44 First Dose M/F: 09/15/04 / 09/16/04

FISCHER 344 RATS MALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG	
Hyperkeratosis				1 [3.0]	
Hyperplasia				2 [3.0]	
Inflammation				1 [3.0]	
Ulcer			1 [4.0]	1 [2.0]	
Control, Hyperkeratosis			. [0]	1 [2.0]	
Control, Hyperplasia				1 [2.0]	
Control, Inflammation				1 [1.0]	
Control, Sebaceous Gland, Hyperplasia				1 [1.0]	
Sebaceous Gland, Site Of Application, Hyperplasia			12 [1.0]	48 [1.1]	
Site Of Application, Hyperkeratosis		2 [1.0]	21 [1.0]	48 [1.6]	
Site Of Application, Hyperplasia		6 [1.0]	20 [1.0]	50 [1.2]	
Site Of Application, Inflammation				46 [1.3]	
Site Of Application, Ulcer				1 [1.0]	
MUSCULOSKELETAL SYSTEM					
Bone	(50)	(50)	(50)	(50)	
Fibrosis	( /	,	,	1 [1.0]	
Hemorrhage		1 [3.0]			
Osteopetrosis				1 [3.0]	
Epiphysis, Femur, Cyst		1 [2.0]			
Mandible, Cyst			1 [4.0]		
NERVOUS SYSTEM					
NERVOUSSISIEM					
Brain	(50)	(50)	(50)	(50)	
Hemorrhage	3 [2.3]	4 [2.8]		2 [2.5]	
Hydrocephalus	2 [1.5]	3 [1.7]	4 [1.8]		
Cerebrum, Inflammation				1 [1.0]	
RESPIRATORY SYSTEM					
	(50)	(50)	(50)	(50)	
Lung	(50)	(50)	(50)	(50)	

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

**Route: SKIN APPLICATION** 

Species/Strain: RATS/F 344/N

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 12/17/2009 AVERAGE SEVERITY GRADES[b]

Pyrogallol **CAS Number:** 87-66-1

Time Report Requested: 08:48:44 First Dose M/F: 09/15/04 / 09/16/04

FISCHER 344 RATS MALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG	
Congestion	1 [3.0]		1 [2.0]		
Hemorrhage	1 [1.0]	3 [3.0]			
Hyperplasia			1 [3.0]		
Inflammation	6 [1.5]	12 [1.6]	13 [1.2]	8 [1.1]	
Metaplasia, Squamous			1 [1.0]		
Pigmentation, Hemosiderin		1 [3.0]			
Thrombosis	2 [1.5]	1 [2.0]			
Alveolar Epithelium, Hyperplasia	9 [1.9]	7 [2.0]	10 [1.8]	6 [1.5]	
Alveolus, Infiltration Cellular, Histiocyte	6 [1.3]	6 [1.5]	5 [1.4]	4 [1.3]	
Bronchiole, Fibrosis			1 [3.0]		
Serosa, Hyperplasia	1 [1.0]		11		
Nose	(50)	(50)	(50)	(50)	
Inflammation	21 [1.5]	28 [2.0]	21 [2.0]	18 [1.9]	
Metaplasia, Squamous	1 [2.0]	[]	[]	[]	
Polyp, Inflammatory	. []	1 [4.0]			
Thrombosis		2 [2.5]			
Nasolacrimal Duct, Inflammation		_ []		1 [2.0]	
Trachea	(50)	(50)	(50)	(50)	
Infiltration Cellular, Mononuclear Cell	()	1 [1.0]	()	()	
Inflammation	1 [1.0]	. []	2 [1.5]		
Metaplasia, Squamous	. []		1 [1.0]		
SPECIAL SENSES SYSTEM					
Eye	(50)	(50)	(50)	(50)	
Cataract	()	2 [2.5]	(/	1 [3.0]	
Anterior Chamber, Inflammation	1 [2.0]	_ [=.0]		. [0.0]	
Cornea, Inflammation	1 [4.0]				
Retina, Atrophy	1 [2.0]	3 [3.0]		1 [3.0]	
Retina, Developmental Malformation	, [=,0]	0 [0.0]	1	. [0:0]	
Harderian Gland	(50)	(50)	(50)	(50)	
Hyperplasia	1 [1.0]	1 [2.0]	2 [2.0]	(00)	
Inflammation	1 [2.0]	1 [3.0]	1 [1.0]	2 [2.0]	
Zymbal's Gland	(1)	(0)	(0)	(0)	
Lymbal o Olaria	(1)	(0)	(0)	(0)	

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

**Route: SKIN APPLICATION** 

Species/Strain: RATS/F 344/N

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 12/17/2009 AVERAGE SEVERITY GRADES[b]

Pyrogallol **CAS Number: 87-66-1** 

Time Report Requested: 08:48:44 First Dose M/F: 09/15/04 / 09/16/04

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG	
URINARY SYSTEM					
Kidney	(50)	(50)	(50)	(50)	
Cyst, Multiple				1 [3.0]	
Hyperplasia, Tubular			2 [1.0]	3 [2.0]	
Inflammation	1 [1.0]	1 [2.0]		2 [2.0]	
Nephropathy	45 [2.0]	47 [2.3]	49 [2.2]	48 [2.3]	
Thrombosis			1 [1.0]		
Pelvis, Calculus Micro Observation Only				1 [2.0]	
Transitional Epithelium, Hyperplasia				1 [3.0]	
Urethra	(0)	(0)	(0)	(1)	
Bulbourethral Gland, Hyperplasia				1 [4.0]	
Urinary Bladder	(50)	(50)	(50)	(50)	
Hemorrhage	. ,			1 [1.0]	
Inflammation		1 [3.0]			
Transitional Epithelium, Hyperplasia		- ·	1 [1.0]	1 [1.0]	

\*\*\* END OF MALE \*\*\*

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

**Route: SKIN APPLICATION** 

Species/Strain: RATS/F 344/N

#### P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 12/17/2009 AVERAGE SEVERITY GRADES[b]

Pyrogallol **CAS Number: 87-66-1** 

Time Report Requested: 08:48:44 First Dose M/F: 09/15/04 / 09/16/04

FISCHER 344 RATS FEMALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
Disposition Summary				
Animals Initially In Study	50	50	50	50
Early Deaths				
Accidently Killed		1		
Moribund Sacrifice	12	7	18	9
Natural Death	9	9	6	10
Survivors				
Natural Death			1	
Terminal Sacrifice	29	33	25	31
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Erosion	1 [1.0]		•	
Inflammation	1 [2.0]		1 [4.0]	2 [1.0]
Thrombosis			1 [2.0]	
Ulcer	1 [4.0]	1 [2.0]	1 [2.0]	
Intestine Large, Colon	(50)	(50)	(50)	(50)
Inflammation	1 [1.0]			
Parasite Metazoan	2	5	2	1
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Parasite Metazoan	3	8	5	5
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Parasite Metazoan	1			
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Inflammation		1 [2.0]	1 [1.0]	
Parasite Metazoan			1	
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Peyer's Patch, Hyperplasia	1 [2.0]			
Serosa, Fibrosis	1 [1.0]			
Liver	(50)	(50)	(50)	(50)
Angiectasis	1 [1.0]	2 [2.0]		3 [2.7]
Atypia Cellular, Focal			1 [1.0]	
Basophilic Focus	31	34	28	34

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

**Route: SKIN APPLICATION** 

Species/Strain: RATS/F 344/N

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 12/17/2009 AVERAGE SEVERITY GRADES[b]

Pyrogallol **CAS Number:** 87-66-1

Time Report Requested: 08:48:44 First Dose M/F: 09/15/04 / 09/16/04

FISCHER 344 RATS FEMALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG	
Clear Cell Focus	9	1	2	4	
Congestion, Diffuse	ŭ	•	_	1 [3.0]	
Degeneration, Cystic		1 [1.0]	1 [1.0]	. [5.5]	
Eosinophilic Focus	2	4	2	1	
Fatty Change	4 [2.5]	1 [3.0]	6 [2.3]	4 [2.5]	
Hematopoietic Cell Proliferation	. [2.0]	1 [1.0]	0 [2.0]	. [2.0]	
Hemorrhage		1 [1.0]	1 [1.0]	1 [1.0]	
Hepatodiaphragmatic Nodule	1	6	3	7	
Inflammation	23 [1.1]	26 [1.2]	10 [1.1]	, 16 [1.1]	
Mixed Cell Focus	5	5	3	4	
Bile Duct, Hyperplasia	10 [1.0]	7 [1.0]	7 [1.0]	7 [1.0]	
Hepatocyte, Hypertrophy	10 [1.0]	1 [2.0]	, [1.0]	7 [1.0]	
Hepatocyte, Necrosis	1 [1.0]	1 [1.0]	3 [2.0]		
Hepatocyte, Regeneration	1 [1.0]	1 [1.0]	1 [3.0]	1 [1.0]	
Hepatocyte, Vacuolization Cytoplasmic	12 [1.3]	15 [1.1]	8 [1.1]	6 [1.2]	
Hepatocyte, Midzonal, Degeneration	1 [1.0]	10[1.1]	0[1.1]	0 [1.2]	
Portal, Fibrosis	4 [1.0]	1 [1.0]	3 [1.0]	1 [1.0]	
Serosa, Fibrosis	1 [1.0]	1 [1.0]	0[1.0]	1 [2.0]	
Mesentery	(8)	(11)	(13)	(10)	
Necrosis	6 [3.0]	11 [3.0]	13 [3.0]	10 [3.0]	
Oral Mucosa	(2)	(2)	(0)	(0)	
Gingival, Cyst	1 [3.0]	1 [4.0]	(0)	(0)	
Gingival, Inflammation	1 [4.0]	1 [4.0]			
Pancreas	(50)	(50)	(50)	(50)	
Basophilic Focus	(50)	1	(00)	(00)	
Acinus, Atrophy	16 [1.4]	13 [2.0]	17 [1.7]	15 [1.5]	
Acinus, Hyperplasia	3 [2.0]	8 [1.6]	1 [3.0]	5 [2.0]	
Duct, Cyst	4 [2.0]	2 [1.5]	2 [3.0]	2 [2.5]	
Salivary Glands	(50)	(50)	(50)	(50)	
Hyperplasia	(00)	(00)	1 [1.0]	(00)	
Inflammation			1 [2.0]		
Mineralization			1 [1.0]		
Stomach, Forestomach	(50)	(50)	(50)	(50)	
Inflammation	1 [1.0]	(30)	2 [1.0]	3 [1.7]	
Ulcer	5 [3.2]	3 [4.0]	7 [3.7]	3 [4.0]	
Epithelium, Hyperplasia	3 [2.0]	ر۰.۰٦	1 [2.0]	3 [2.3]	

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

**Route: SKIN APPLICATION** 

Species/Strain: RATS/F 344/N

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 12/17/2009 AVERAGE SEVERITY GRADES[b]

Pyrogallol **CAS Number:** 87-66-1

Time Report Requested: 08:48:44 First Dose M/F: 09/15/04 / 09/16/04

FISCHER 344 RATS FEMALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
Stomach, Glandular	(50)	(50)	(50)	(50)
Erosion	1 [3.0]	1 [3.0]	1 [3.0]	,
Inflammation	2 [1.5]		1 [4.0]	2 [1.0]
Ulcer			1 [4.0]	
Epithelium, Cyst				1 [1.0]
CARDIOVASCULAR SYSTEM				
Blood Vessel	(50)	(50)	(50)	(50)
Thrombosis			1 [4.0]	
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	44 [2.0]	45 [1.7]	46 [2.1]	45 [1.4]
Inflammation	1 [1.0]			
Atrium, Thrombosis	1 [3.0]	1 [4.0]	1 [4.0]	
Myocardium, Inflammation		1 [1.0]		
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Angiectasis			1 [2.0]	
Atrophy			1 [3.0]	1 [2.0]
Atypia Cellular			1 [1.0]	
Degeneration, Cystic	8 [2.1]	4 [2.5]	4 [2.3]	2 [2.0]
Hematopoietic Cell Proliferation	1 [2.0]			1 [2.0]
Hemorrhage				2 [2.5]
Hyperplasia	29 [1.6]	24 [1.5]	26 [1.6]	29 [1.8]
Hypertrophy	17 [1.2]	15 [1.5]	24 [1.5]	21 [1.4]
Necrosis			1 [3.0]	
Thrombosis			1 [1.0]	
Vacuolization Cytoplasmic	14 [1.6]	13 [1.5]	13 [1.3]	18 [1.8]
Adrenal Medulla	(50)	(50)	(50)	(50)
Hyperplasia	5 [1.4]	1 [1.0]	6 [1.2]	4 [1.3]
Infiltration Cellular, Mononuclear Cell				1 [2.0]
Islets, Pancreatic	(50)	(50)	(50)	(50)
Parathyroid Gland	(49)	(49)	(50)	(49)

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

**Route: SKIN APPLICATION** 

Species/Strain: RATS/F 344/N

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 12/17/2009 AVERAGE SEVERITY GRADES[b]

Pyrogallol **CAS Number:** 87-66-1

Time Report Requested: 08:48:44 First Dose M/F: 09/15/04 / 09/16/04

Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG	
Hyperplasia			2 [2.0]		
Pituitary Gland	(50)	(50)	(50)	(50)	
Angiectasis	(00)	(00)	1 [2.0]	(00)	
Cyst			1 [3.0]	1 [3.0]	
Hemorrhage	1 [3.0]		[]	2 [3.0]	
Pars Distalis, Cyst	4 [3.8]	8 [3.1]	7 [3.0]	7 [3.3]	
Pars Distalis, Hyperplasia	19 [2.4]	16 [2.6]	17 [2.4]	19 [2.9]	
Pars Distalis, Inflammation		1 [1.0]			
Thyroid Gland	(50)	(50)	(50)	(50)	
Cyst				1 [3.0]	
C-cell, Hyperplasia	22 [1.5]	31 [1.4]	23 [1.5]	31 [1.7]	
Follicle, Cyst		1 [2.0]			
Follicular Cell, Hyperplasia				1 [1.0]	

#### **GENERAL BODY SYSTEM**

None

GENITAL SYSTEM				
Clitoral Gland	(50)	(50)	(50)	(50)
Atrophy			1 [3.0]	
Fibrosis			1 [3.0]	
Hyperplasia	3 [3.0]	1 [3.0]	4 [2.8]	1 [4.0]
Inflammation	3 [2.0]	4 [2.3]	6 [2.2]	6 [2.2]
Duct, Dilatation	1 [4.0]		2 [3.0]	
Ovary	(50)	(50)	(50)	(50)
Cyst	3 [2.3]	3 [3.0]	6 [2.5]	1 [3.0]
Uterus	(50)	(50)	(50)	(50)
Hemorrhage		1 [4.0]		
Hyperplasia, Adenomatous				1 [4.0]
Inflammation	3 [2.3]			1 [4.0]
Cervix, Fibrosis	1 [4.0]			
Endometrium, Cyst			1 [3.0]	
Endometrium, Edema			1 [4.0]	

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 12/17/2009 AVERAGE SEVERITY GRADES[b]

Test Type: CHRONIC

Route: SKIN APPLICATION

Species/Strain: RATS/F 344/N

Pyrogallol CAS Number: 87-66-1

Time Report Requested: 08:48:44 First Dose M/F: 09/15/04 / 09/16/04

FISCHER 344 RATS FEMALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG	
Endometrium, Hyperplasia, Cystic Vagina Inflammation	5 [1.8] (0)	5 [2.0] (1) 1 [4.0]	4 [1.8] (0)	(0)	
HEMATOPOIETIC SYSTEM					
Bone Marrow	(50)	(50)	(50)	(50)	
Fibrosis	1 [2.0]				
Hyperplasia	10 [3.1]	6 [3.8]	10 [4.0]	10 [3.8]	
Myelofibrosis			2 [2.5]	1 [3.0]	
Lymph Node	(3)	(2)	(4)	(2)	
Hemorrhage			1 [3.0]		
Deep Cervical, Hyperplasia, Plasma Cell	1 [3.0]				
Mediastinal, Congestion		1 [3.0]			
Mediastinal, Hemorrhage	2 [3.0]		1 [3.0]		
Mediastinal, Hyperplasia, Plasma Cell	1 [2.0]	1 [3.0]	1 [2.0]		
Pancreatic, Hemorrhage			1 [4.0]		
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)	
Degeneration, Cystic	3 [2.0]			1 [2.0]	
Hyperplasia, Lymphoid				1 [3.0]	
Hyperplasia, Plasma Cell			1 [2.0]	1 [2.0]	
Infiltration Cellular, Histiocyte		1 [3.0]			
Inflammation		2 [1.5]			
Spleen	(50)	(50)	(50)	(50)	
Accessory Spleen			1	1	
Hematopoietic Cell Proliferation		3 [2.3]	1 [3.0]		
Hyperplasia, Lymphoid		1 [3.0]	1 [3.0]	2 [2.5]	
Infarct		2 [3.0]	4 [3.0]	1 [4.0]	
Pigmentation, Hemosiderin		1 [2.0]		1 [2.0]	
Capsule, Hyperplasia			1 [1.0]		
Capsule, Inflammation			1 [1.0]		
Lymphoid Follicle, Atrophy		1 [2.0]	1 [2.0]	1 [2.0]	
Thymus	(50)	(50)	(49)	(50)	
Cyst				1 [3.0]	

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

**Route: SKIN APPLICATION** 

Species/Strain: RATS/F 344/N

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 12/17/2009 AVERAGE SEVERITY GRADES[b]

Pyrogallol **CAS Number:** 87-66-1

Time Report Requested: 08:48:44 First Dose M/F: 09/15/04 / 09/16/04

FISCHER 344 RATS FEMALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG	
INTEGUMENTARY SYSTEM					
Mammary Gland	(50)	(50)	(50)	(50)	
Inflammation	1 [3.0]	4 [2.3]		1 [1.0]	
Duct, Cyst	1 [4.0]	1 [4.0]	1 [3.0]	5 [3.4]	
Duct, Hyperplasia, Cystic	1 [3.0]				
Skin	(50)	(50)	(50)	(50)	
Hyperkeratosis		2 [1.0]	1 [1.0]		
Hyperplasia				1 [4.0]	
Ulcer				1 [4.0]	
Control, Hyperplasia			1 [1.0]		
Control, Inflammation			1 [1.0]		
Sebaceous Gland, Site Of Application, Hyperplasia			5 [1.0]	41 [1.7]	
Site Of Application, Hyperkeratosis		6 [1.0]	22 [1.0]	49 [1.8]	
Site Of Application, Hyperplasia		9 [1.0]	11 [1.0]	49 [1.1]	
Site Of Application, Inflammation		3 [1.0]	6 [1.0]	49 [1.4]	
MUSCULOSKELETAL SYSTEM					
Bone	(50)	(50)	(50)	(50)	
Osteopetrosis	,	, ,	1 [4.0]	, ,	
Osteosclerosis	1 [2.0]				
Fibula, Tibia, Fracture	1 [4.0]				
Skeletal Muscle	(0)	(0)	(2)	(0)	
NERVOUS SYSTEM					
Brain	(50)	(50)	(50)	(50)	
Hemorrhage	1 [3.0]	1 [3.0]	(/	1 [3.0]	
Hydrocephalus	1 [2.0]	3 [1.7]	3 [1.7]	3 [2.0]	
Thrombosis	[]	- [ ]	1 [2.0]	- 1 -1	
Cerebellum, Gliosis	1 [1.0]		r - 1		
Cerebrum, Necrosis	1 [3.0]				

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

**Route: SKIN APPLICATION** 

Species/Strain: RATS/F 344/N

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 12/17/2009 AVERAGE SEVERITY GRADES[b]

Pyrogallol **CAS Number:** 87-66-1

Time Report Requested: 08:48:44 First Dose M/F: 09/15/04 / 09/16/04

Species/Strain. NATS/F 344/N				Lab. DAT		
FISCHER 344 RATS FEMALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG		
RESPIRATORY SYSTEM						
Larynx	(0)	(1)	(0)	(0)		
Foreign Body		1				
Inflammation		1 [2.0]				
Lung	(50)	(50)	(50)	(50)		
Congestion		1 [4.0]	1 [3.0]	1 [2.0]		
Fibrosis	2 [1.0]					
Hemorrhage		2 [3.0]				
Inflammation	8 [1.3]	9 [1.0]	2 [1.0]	10 [1.1]		
Thrombosis	1 [1.0]					
Alveolar Epithelium, Hyperplasia	6 [2.0]	11 [2.3]	5 [1.8]	12 [2.3]		
Alveolus, Infiltration Cellular, Histiocyte	2 [2.0]	3 [1.0]	2 [1.5]	6 [1.5]		
Alveolus, Pigmentation, Hemoglobin				1 [1.0]		
Bronchiole, Hyperplasia				1 [2.0]		
Serosa, Fibrosis		1 [1.0]				
Nose	(50)	(50)	(50)	(50)		
Inflammation	11 [1.7]	10 [2.3]	12 [2.2]	8 [2.0]		
Metaplasia, Squamous	1 [1.0]	1 [1.0]				
Thrombosis	1 [3.0]	1 [3.0]	1 [3.0]			
Goblet Cell, Hyperplasia	2 [1.5]	2 [1.5]				
Nasolacrimal Duct, Inflammation		1 [3.0]				
Nasolacrimal Duct, Squamous Epithelium, Hyperplasia	1 [3.0]					
Nasopharyngeal Duct, Inflammation			2 [2.5]			
Olfactory Epithelium, Hyperplasia			1 [2.0]			
Respiratory Epithelium, Necrosis		1 [2.0]				
Squamous Epithelium, Necrosis		1 [1.0]				
Vomeronasal Organ, Necrosis		1 [3.0]				
Trachea	(50)	(50)	(50)	(50)		
Infiltration Cellular, Mononuclear Cell	1 [1.0]					
Inflammation	1 [1.0]		1 [1.0]			

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

**Route: SKIN APPLICATION** 

Species/Strain: RATS/F 344/N

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 12/17/2009 AVERAGE SEVERITY GRADES[b]

Pyrogallol **CAS Number:** 87-66-1

Time Report Requested: 08:48:44 First Dose M/F: 09/15/04 / 09/16/04

FISCHER 344 RATS FEMALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG	
SPECIAL SENSES SYSTEM					
Eye	(50)	(50)	(50)	(50)	
Cataract	3 [3.0]	4 [3.5]	1 [4.0]	1 [3.0]	
Synechia	1 [3.0]	1 [2.0]			
Anterior Chamber, Exudate				1 [3.0]	
Bilateral, Retina, Atrophy		1 [4.0]			
Optic Nerve, Atrophy	1 [3.0]		1 [4.0]		
Posterior Chamber, Exudate				1 [3.0]	
Retina, Atrophy	3 [4.0]	3 [3.3]	2 [3.0]		
Retina, Developmental Malformation	1 [1.0]				
Retina, Dysplasia		1 [2.0]		1 [3.0]	
Harderian Gland	(50)	(50)	(50)	(50)	
Hyperplasia	1 [1.0]	2 [2.0]	4 [2.8]	3 [2.3]	
Inflammation	2 [1.0]	4 [1.5]	1	4 [1.5]	
Metaplasia, Squamous	1 [1.0]				
Pigmentation, Porphyrin		3 [2.0]	6 [1.8]	1 [3.0]	
URINARY SYSTEM					
Kidney	(50)	(50)	(50)	(50)	
Accumulation, Hyaline Droplet	(00)	2 [2.0]	(00)	(00)	
Atrophy		2 [2.0]	1 [3.0]		
Cyst		1 [2.0]	1 [1.0]		
Hypertrophy		. [2.0]	1 [2.0]		
Infiltration Cellular, Lipocyte		1 [4.0]	. [2.0]		
Inflammation	1 [1.0]	. [•]	3 [2.7]		
Nephropathy	46 [1.5]	42 [1.7]	42 [1.6]	44 [1.6]	
Papilla, Necrosis	.0[0]	[]	1 [3.0]	[0]	
Transitional Epithelium, Hyperplasia			1 [2.0]		
Urinary Bladder	(50)	(50)	(50)	(49)	
Transitional Epithelium, Hyperplasia	(00)	1 [1.0]	1 [1.0]	(10)	

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

### P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 12/17/2009 AVERAGE SEVERITY GRADES[b]

Pyrogallol CAS Number: 87-66-1

Time Report Requested: 08:48:44

First Dose M/F: 09/15/04 / 09/16/04

Lab: BAT

Route: SKIN APPLICATION Species/Strain: RATS/F 344/N

**FISCHER 344 RATS FEMALE** 

TO DATO/F 044/N

0 MG/KG 5 MG/KG 20 MG/KG 75 MG/KG

\*\*\* END OF REPORT \*\*\*